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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/224,781	01/04/99	LIBIN B	1059-007

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1614	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/224781	Applicant(s) LIBIN
	Examiner SHEP ROSE	Group Art Unit 1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on ACCEPTED T.D. AND AMENDMENT 12/23/99.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☐ Claim(s) 1 7 18 & 25 27 & 30 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1 7 18 & 25 27 & 30 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☒ Claim(s) 1 7 18 & 25 27 & 30 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

Applicant's Terminal Disclaimer has been accepted, obviating the obviousness-type double patenting ground of rejection on U.S. Patent 5,945,089, the patent which issued on claims 1-5 of applicant's 09/186,825, the subject of the outstanding ground of rejection set forth on pages 2-5 of the July 19, 1999 Office action.

Subsequent to the mailing of the Office action, a personal interview was conducted on August 19, 1999. At that interview it was agreed that a Terminal Disclaimer would be filed. Present at the interview, with applicant: Barry Libin, and his attorney, James Costigan, with the undersigned USPTO Examiner (Shep Rose), was USPTO Reference Librarian Jan Delaval, who explained how she selected the appropriate databases that led to her discovery of pertinent non-patent literature cited on the PTO-892 "Notice of References Cited", describing the treatment of mucositis, fungal infections (candiasis), and/or herpetic virus infections, and their symptoms, i.e. inflammation, by treatment with cationic antimicrobial agents, like "CHX", (chlorhexidine), if not with Triclosan, "T", the subject of the Libin patent 5,945,089 (noted above), which has been overcome by USPTO acceptance of the Terminal Disclaimer.

Jan Delaval had also conducted database searches that led to the discovery of the eight (8) foreign patents cited on the PTO-892, each admixing the two antimicrobials: Triclosan (T),

with cationic antimicrobial agents, like "CHX", chlorhexidine, "CPC" (cetylpyridinium chloride", "BZ" (benzothonium chloride), and other cationic "QA" quaternary ammonium compounds.

On January 3, 2000, applicant filed and made of record some of EPO cited patent references based on a European counterpart application, and some of these do mention the treatment of fungal and/or herpetic infections as do the literature citations (noted above), discovered by USPTO Librarian Jan Delaval.

Unilever EP 528486A1 (2/93), U.S. 5,240,696 (8/93), makes no mention of fungal or herpetic infections but describes a Triclosan for the treatment of periodontitis, with additional antibacterial agents: Quaternary ammonium compounds such as: cetylpyridinium chloride, bisbiguanides such as chlorhexidine gluconate, etc.

Fabulon, WO 93/25209 (12/93) treats herpes infection and skin inflammation caused by it with Triclosan (Irgasan), with no mention of cationic antimicrobial agents.

Takaoka, GB 2160099 (12/85), treats a fungal infection, (athletes foot), with Triclosan, and with no mention of cationic antimicrobial agents.

Gaffar et al. U.S. 5,279,813 (1/94), describes an anti-plaque oral composition which can be a liquid semi-solid gel or paste, with fluoride and with Triclosan, to which may be added other such non-cationic antibacterial agents, with no mention of

cationic antimicrobial agents, fungal infections or anti-herpetic virus, but which meets claim 7 herein.

Claims 2-6, 8-17 and 26 have been cancelled.

Claims 1 and 23 have been amended.

Claim 1 has been amended to delete mucositis, but remains to treat fungal infections or herpetic infections, by contacting the affected disease sites (not necessarily oral or of the oral mucosa) (page 1 lines 14 and 15), and which may be caused by herpes (page 1, line 25 et seq. to page 2, line 34), or fungi, the fungi being the cause of dermal, mucosal, or periodontal opportunistic infections (page 2, line 35 et seq.), in immunal compromised patients (page 3, lines 1-5), such as those suffering from HIV infections, transplant recipients treated with immunosuppressive drugs, and cancer patients undergoing chemotherapy and/or radiation therapy.

The USPTO librarian, Jan Delaval, present at the personal interview, discovered the cited non-patent literature describing cationic antimicrobial agents to treat such patients in the "Cancerlit", and "Medlin" and other databases.

Applicant's specification, on page 3 lines 6-12, cites as admitted prior art, Guiliana et al., Journal of Periodontology Volume 68 pages 791-801 (1997) as admittedly describing mouth rinses of either of Triclosan or of "CPC" (cetylpyridinium chloride), cationic antimicrobial agent, as appropriate

alternatives to treat oral candidiasis, an encompassed species of fungal infections.

Claims 1 and 18-22 are drawn to treat herpetic infection disease sites with both Triclosan and a cationic antimicrobial agent, and present a question of obviousness-type double patenting on Libin U.S. 5,855,872, claims 1-10.

Claims 23-30 are drawn to treat fungal infections with both Triclosan and a cationic antimicrobial agent.

Claim 7 is drawn to a composition, semi-solid gel or paste or liquid, for treating mucositis comprising Triclosan and fluoride, as in the Gaffar patent U.S. 5,279,813, cited by the EPO and made of record by applicant herein.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 7 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gaffar U.S. 5,279,813.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 18-22 are rejected under the judicially created doctrine of double patenting over claims 1-10 of U. S. Patent No. 5,855,872 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: treating herpetic disease sites with both

Triclosan and a cationic antimicrobial agent and overlap in scope.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1 and 18-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending application Serial No. 5,855,872. Although the conflicting claims are not identical, they are not patentably distinct from each other because treating herpetic disease sites with both Triclosan and a cationic antimicrobial agent and overlap in scope.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 23-30 are claims which are drawn to treating fungal disease sites with compositions comprising both the Triclosan and the cationic antimicrobial agent.

Claims 1 and 23-30 are rejected under 35 U.S.C. 103(a) as being obvious as a whole from the combination of: applicant-cited Takaoka, GB 2160099 (12/85), taken in combination with the cationic antimicrobials such as in the non-patent literature

cited on the PTO 892 of record, especially Levy (I) September 1998 (CHX - oral candiasis); Cancro (III) (August 1994) (CHX - anticandida); Greenspan (IV) (August 1994) (CHX - oral candiasis); Poland (A) (1987) (CHX - opportunistic fungi, candida); Ferratti et al. (9), (10) (1987), (CHX - candiasis-candida albicans); Costiala (1982), (CHX - patients with oral fungi, yeast, candida albicans, 25% reduction); Budtz-Jorgenson (December 1997) (CHX - significant amelioration reduction of oral candiasis inflammation) and the combination taken in further view of prior patent art combining both of the two antimicrobial agents, Triclosan and cationic antimicrobial agents employed together as described in the foreign patents cited on the PTO-892, namely:

Veb East Germany 221080 (4/80) (emulsion or lotion of TMCHX, Triclosan and chlorhexidine);

Gluck (I) WO 86/05391 (9/86) (skin disinfectant mixtures, claim 4, of T, CHX, CPC, BZC, etc. (Triclosan, chlorhexidine, cetylpyridinium chloride, benzylconium chloride);

Gluck (II) WO 93/07250 (4/93) (skin disinfectant mixtures - claim 7 of: T plus CHX, (Triclosan and chlorhexidine);

Hill EP 679390 (11/95) (column 1 lines 1-17, column 2 lines 13-26): mixture of two or more of: Triclosan, quaternary ammoniums: benzylconium, cetylpyridinium chloride,

chlorhexidine, for mucus membranes and skin infections and to treat symptoms associated with cold sores (claim 10), or herpes virus;

Livingston Canada 2132688 (3/96) (vaginal gel of Triclosan and benzylconium chloride, 0.05% to 2% of each, to protect vaginal mucus membranes against herpes virus, bacterial disease, microbacteria, etc. (page 1 lines 9-14, page 4 lines 17-18, page 7 lines 10-15.

Claims 1 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Livingston and Hill (details against herpes infections as noted above).

PRIOR ART ADMISSIONS

An admission relating to the prior art is a fact which is a part of the scope and content of the prior art which every examiner is required to consider. Ex parte McGaughey, 6 USPQ 2d 1334, at 1338/1339, In re Thompson 192 USPQ 275, In re Nomiwa 184 USPQ 607, In re Davis, 134 USPQ 256, 285.

OBVIOUS COMBINATION CASE LAW

As stated in In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA-1980):

". . . It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in Crockett, 126 USPQ 186, 188 (CCPA-1960), the idea of combining them flows logically from their having been individually taught in the prior art.

Likewise, see: In re Pinten, 173 USPQ 801, 803 (CCPA 1972); and In re Susi, 169 USPQ 423, 426 (CCPA-1971).

Applicant's attention is directed to legal decisions, binding on USPTO patent examiners, on a vital issue of "new use" of known compositions.

Ex parte Novitski, 26 USPQ 2d 1389 (January 22, 1993), is a decision of the USPTO Board of Appeals, holding to be inherent and not patentable, inoculating healthy plants with a known plant inoculant, heretofore employed in the prior art to protect them against phytopathogenic fungi. Novitski discovered that the known plant inoculant would also protect them against root dwelling plant pathogenic nematodes, a discovery neither known nor appreciated. Nevertheless, the step of inoculating plants with the same inoculant necessarily and inherently protects them against nematodes.

Atlas Powder versus Ireco, 51 USPQ 2d 1943, (Fed. Cir.-1999), holds that the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not precluding a finding of anticipation. Whether or not an element is inherent in the prior art, is a fact question. Inherency is not necessarily coterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition does not render the old composition patentably new to the discoverer. The fact that the prior art taught away from the claim is, in fact, only "a showing that the prior art did not recognize the inherent function. This lack of contemporary understanding did not defeat the showing of inherency.

A review of applicant's specification reveals no in vitro or in vivo data establishing more than the expected additive effect of combining the two antimicrobials and then applying this known combination to the disease sites of a fungus or herpes infection.

Claims 1, 7, 18-25 and 27-30 are generic to a plurality of disclosed patentably distinct species comprising

One species each of:

(a) A cationic antimicrobial agent species;

(b) a species of disease selected from one of: mucositis (claim 7), or fungus disease infection, or herpetic infection.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, of each even though this requirement is traversed. If this application is filed under Rule 371, the legal authority is PCT Rule 13.2, Annex B, Part 1(f) "Markush Practice"; PCT Rule 13 and 35 U.S.C. § 372, rather than 35 U.S.C. § 121.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be

obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of species is required per MPEP § 803, 809.02(d) (Markush group claim practice, separate and burdensome fields of search required).

Patentably distinct Markush species are independent inventions, In re Webber, 198 USPQ 328, In re Haas, 198 USPQ 334. Divisional applications may be filed under 35 U.S.C. § 121, as a result of an Office requirement for an election of a patentably distinct species as made herein. In re Joyce, 115 USPQ 412, In re Herrick, 115 USPQ 412. This satisfies the "patentably distinct" criterion since the Examiner is not of the opinion that the various species are obviously unpatentable over one another, and each species (as noted above) is capable of independent manufacture, use, and sale, with the other components of the claimed formulations.

Applicant is further required to identify the claims that correspond to the elections as well as those that do not even if the requirements are traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Shep Rose
Senior Primary Examiner
Art Unit 1614

SKR:cdc
March 1, 2000

SHEP K. ROSE
PRIMARY EXAMINER
GROUP 1200